PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Jill McFadden et al.	Confirmation No.:	2472
Serial No.:	09/097,023	Examiner:	Elizabeth MacNeill
Filing Date:	June 12, 1998	Group Art Unit:	3767
Docket No.:	1001.1566101	Customer No.:	28075
For:	CATHETER WITH KNIT SECTION		

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

CERTIFICATE FOR ELECTRONIC TRANSMISSION:
The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 20th day of November 2008.

By Kathleen L Boekley
Kathleen L. Boekley

Dear Sir:

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this Request.

This Request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached five sheets of arguments.

This Request is signed by an attorney or agent of record.

Respectfully submitted,

Jill McFadden et al.

By their Attorney,

Date: 11/20/08

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Attachment: Five Sheets of Pre-Appeal Brief Request Attachment

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PRE-APPEAL CONFERENCE BRIEF

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By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Applicants have carefully reviewed the Final Office Action dated July 29, 2008 and the Advisory Action dated October 10, 2008. Currently claims 51 and 52 are pending in the application, wherein claims 51 and 52 have been rejected. Applicants hereby request a pre-appeal conference and file this Pre-Appeal Conference Brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 51 and 52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Samson, U.S. Patent No. 5,702,373 in view of Andersen et al, U.S. Patent No. 5,662,713. Applicants respectfully traverse this rejection, asserting a *prima facie* case of obviousness has not been established. Applicants submit that the Examiner's rejection contains at least the following errors and/or omissions of one or more essential elements needed for a *prima facie* rejection.

Independent claim 51 recites:

> 51. A catheter comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between those ends, said elongate tubular member comprising:
>
> a relatively stiff proximal segment including an inner proximal liner, an outer proximal cover, and a braid interposed between the inner proximal liner and the outer proximal cover; and
>
> a relatively flexible distal segment comprising a knit tubular member and an inner tubular liner in coaxial relationship with the knit tubular member, wherein the knit tubular member is formed from a single strand, wherein the single strand forms a plurality of up loops and a plurality of down loops, wherein the plurality of up loops of the single strand interlock with the plurality of down loops of the single strand;
>
> wherein the knit tubular member is generally not radially expandable.

Nowhere do Samson or Andersen et al., either alone or in combination, teach or suggest "a knit tubular member [which] is formed from a single strand...wherein the knit tubular member is generally not radially expandable," as currently claimed. Independent claim 52 also includes similar limitations.

Applicants assert Samson is not believed to teach a knit. Samson teaches that the component denoted with reference number 244 is an inner braid of the catheter shown in FIG. 7. See Samson, at column 13, lines 45-61.

Samson is quite clear when describing a braid as indicated by the description when it is stated:

> Whenever I use the term "braid" herein, I mean tubular constructions in which the ribbons making up the construction are woven in an in-and-out fashion as they cross to form a tubular member defining a single lumen. The braids may be made up of a suitable number of ribbons, typically six or more.

Samson, at column 12, lines 15-20 (emphasis added).

Furthermore, Applicants assert Andersen et al. fail to teach a knit tubular member which is not generally radially expandable, as currently claimed. Instead, Andersen et al., which the Examiner relies on for its teaching of a knit made of single fiber, teach a stent for reinforcement of the lumen of a peristaltic organ, such as the esophagus. Andersen et al. teach the stent is formed by knitting a wire into a pattern of overlapping loops such that in a relaxed state each row of loops may shift axially relative to and independent of the rows on either side accommodating

peristalsis of the organ. See Andersen et al. at Abstract. This movement allows the stent to be placed into the lumen of a peristaltic organ without the stent migrating within the organ. Thus, Andersen et al. need the stent to be capable of expansion and contraction in order for the device to function as intended. Andersen et al. teach at column 3, line 65 through column 4, line 7:

> The rows of loops of the stent shift axially with elastic deformation of the wire of the loops so that the separation of the heads increases to a loop length l_1, as shown in FIG. 1e. In the region of maximum expansion 150, the length of each portion of the esophagus returns to its rest length, but the diameter is extended. The knit loops of the stent can widen, as shown in FIG. 1f, to accommodate this extension. Returning again to considering any peristaltic organ, the organ contracts (c of FIG. 1c) to compress a region.

FIG. 1c of Andersen et al. has been reproduced below to facilitate the discussion.

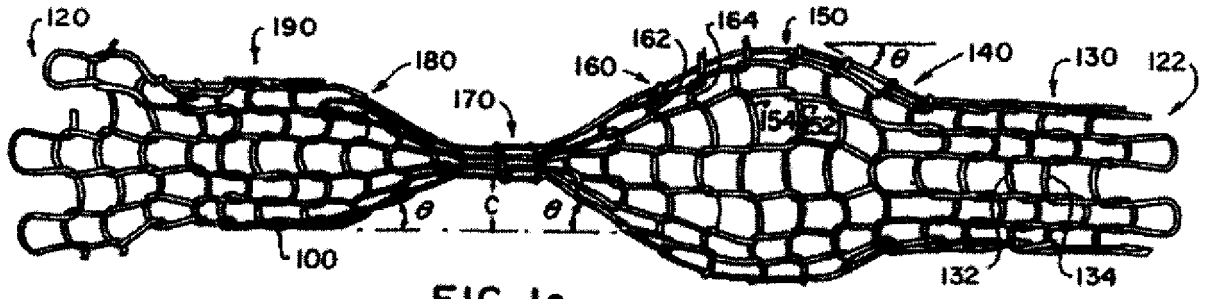

FIG. 1c

Andersen et al. intend the stent to radially expand and contract as shown in Figure 1c above to complement the peristaltic motion of the esophagus. Indeed, the title of the patent to Andersen et al. is "Medical Stents for Body Lumens Exhibiting Peristaltic Motion."

Further, while FIG. 9 of Andersen et al. shows the stent in a delivery position while disposed within a catheter, this is for the delivery of the stent to the desired location. Once the stent is deployed from the delivery catheter, the stent radially expands. This expansion of the stent is shown in FIGS. 9a and 9b. Andersen et al. state "In FIG. 9a, the sleeve is removed from about the stent...thus allowing the stent 100 to radially expand by release of its internal restoring force." Andersen et al. at column 11, lines 21-24 (emphasis added). Thus, the stent is indeed expandable, as this feature is necessary for the stent to function properly as discussed in Andersen et al.

From the foregoing, it seems apparent that Andersen et al. teach away from the claimed invention. As the Examiner is aware, MPEP §2141.02 VI states, "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)." The Supreme Court has recently reaffirmed that when the prior art teaches away from a suggested direction of analysis, a finding of nonobviousness can be ascertained. See *KSR Int'l Co. v. Teleflex Inc.*, 550 US ___, 82 USPQ2d 1385 (2007).

In responding to Applicants' showing that the knitted stent of Andersen et al. is indeed expandable, in the Advisory Action the Examiner stated "Because the knit of Anderson is constrained by the liner of Samson, it is not capable of expanding in the catheter." Applicants respectfully disagree with this statement. Because an expandable member is located within another member doesn't render the expandable member unexpandable. Being constrained from expanding and being unexpandable are clearly not equivalent.

An illustration of a balloon may help express Applicants' point. It is well understood that a balloon is expandable. Because the balloon is purchased with a package surrounding the balloon doesn't render the balloon unexpandable. Clearly, the balloon may be expanded when one puts the balloon to one's mouth and blows air into the balloon. The structure of the balloon has not changed. The balloon, at all times, is expandable.

Applicants respectfully assert that it is the knit tubular member which is claimed as being generally not radially expandable, not the portion of the catheter in which the knit tubular member is located as seems to be suggested in the Advisory Action.

Further of the Examiner's erroneous assertion, neither claim 51 nor claim 52 expressly state any outer layer or member around the claimed "knit tubular member". Thus, the reliance on the middle layer of polymeric tubing 254 of Samson as constraining the knit of Andersen et al. as providing the means for rendering the knitted stent of Andersen "not capable of expanding" is unfounded.

As currently claimed, the knit tubular member is generally not radially expandable, regardless of whether an outer layer surrounding the knit tubular member is present or not.

In view of the foregoing, all pending claims, namely claims 51 and 52, are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Jill McFadden et al.

By their Attorney,

Date: 11/20/08

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